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GO THE MEDICAMENT DISPERSING DEVICE				
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## REDICAMENT DISPENSING DEVICE

This invention relates to a dispensing device, and more specifically, to a device suitable for dispensing discrete enounts of fluid.

In particular, the invention is concerned with a dispensing device of the type where the metered dose is administered in response to the inhalation of the patient.

Notered dose inhalers are wall known in medicine for ent, or alleviation of the effects of respiratory complaints, for example asthma. Breath-actuated devices are also known, and have been the subject of many patent applications.

GR 1288971; GR 1297993; GR 1335178; GR 1382761; GR 1392192; GB 1413285; W085/01880; GB 2204799; US 4803978 and EP 0186280% describe inhalation-actuated dispensing devices for use with a pressurised excess) dispensing container. The device includes a dispensing container and the <u>container includes</u> a valve capable of releasing a metered amount of the exropol-contents, when an internal spring operating the valve is compressed by a sufficient arount. The dispensing device often commrises a chamber having a mouthpiece, air inlete, actuating means for causing the actuation of the valve in the dispensing container, a latching means for releasably retaining said setering valve in a charged position, and an inhalation responsive means for releasing the latch, such that a netered amount of aerosol compound is discharged into the region of the postimiece. The overall objective is to give co-ordination of discharge of pedicament from the erosol container with inhalation of the petient, thus allowing a nazimus dose of sedicment to reach the bronchial passages of the lungs.

The latching means is often connected to a valve which moves from a latching position to a dispensing position in response to a partial vacuum developed upon ichalation.

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EP-A-0045419 describes an inhalation device having blassing means which are alone of insufficient force to depress the container but which together are of sufficient force to do so.

EP-A-186280 describes a device which employs namets to control the release of the serosol container.

US 3605738 describes devices in which the aerosol container communicates with the nouthpiecs via a metering chamber. A metered quantity of the aerosol compound is discharged into the netering chamber and this is conveyed to the mouthplace via an inhalation-actuated valva.

GB 1269554 describes a device wherein the serosol container is movemble by a lever and cam system into a charged position held by a latch, a pressure differential acting to trip the latch and move the valve of the container to a discharge position.

It is the object of this invention to provide a netered dose inhaler, wherein the release of the nedicament is actuated by the inhalation of the potient. It is a further object of the invention to provide an inhalation-ectuated device which is more simple and compact than the prior art dispensers.

According to one aspect of the present invention there is provided a dispensing device for use with a drug delivery system comprising a peams for releasing a measured dose of medicament from the system, the releasing means comprising a means for applying a preload capable of actuating the dalivery means in the system, a means for applying a resisting possmotic force capable of preventing actuation of the delivery means and a release device capable of freeing the resisting prematic force to allow the oreland to actuate the delivery means and dispense the nedicanent.

The pneumatic resisting means may be provided by air which is either held at a positive pressure greater than

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atmospheric or a negative pressure below atmospheric prior to release. The release device will act to return the pressure to atmospheric or prior equilibrium, thus allowing the full force of the preload to act.

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The device is particularly suited for use with pressurised inhelation carosols having valves as the dalivery mans.

Although this device has been described in particular relation to a system using air, it will be realised that in a closed system any suitable gas could be used.

In a preferred arrangement, there is provided a receptable for an aerosol dispensing container. The receptacle may comprise an outer chamber having a southpiece to allow inhalation by a patient using the device. The receptable may further include one or nowe air inlets to allow air to pass to the mouthpiecs. An inner sleeve enclosing the main hody of the serosol container may be included within the outer chamber. The outer chamber is defined at one end by a cross sember which accompdates the valve of the aerosol and seals the chamber spart from providing an serosol outlet. The inner sleeve is preferably sealed such that there is aliding air tight contact with the outer chamber such that the serosol container and immor housing provide a piston effect against the cross member to form the resisting load in the form of a high pressure volume capable of preventing the actuation of the serosol valve.

In a further preferred arrangement, there is provided a receptable for the exceed dispensing container. The receptable may comprise an outer chamber having a southplace to allow imbalation by a patient using the devices. The receptable may further include one or more air inlets to allow air to pass to the mouthplace. An inner sleeve enclosing the top portion of the main body of the serosol container may be included within the outer chamber. This inner sleeve is preferably arranged to form one and of an air tight piston cylinder, bellows or

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a vacuum or mear vacuum, opening of the valve port allows air to enter the enclosed volume, again allowing the full force of the preload to act against the aerosol valve.

The favoured hreath-actuating means comprises a novemble was enchanism. This was mechanism may be housed in the lower or upper part of the chember, depending upon the location of the resisting element. A valve seal is preferably attached to said wase, such that on inhalation the wase noves from its rest position to its actuating position, thus nowing the valve seal out of contact with the valve port, causing the opening of the valve. The vane mechanism is preferably dynamically belanced, and say be biased towards its closed position, e.g. by a spring.

The outer chamber may include air inlets allowing passage of air to the mouthpiece of the device. The inlets may take the form of slots or of an air perces membrane. The letter is particularly suitable to halp filter dust.

The medicament may be a drug per so or on any form of carrier, e.g. including a powder or a gaseous carrier.

The invention will now be described by way of example only, with reference to the accompanying drawings, in which:-

Figure 1 is a section view of an inhaler, according to a first embodiment of the invention, in the rest position;

Figure 2 is a section view of an inhalar according to the first embodiment of the invention during inhalation actuation;

Figure ) is a section view of an inhalar according to a second embodiment of the invention.

Figure 4 shows an enlarged view of a disphrage for use with the embodiment above in Figure 3.

Figure 5 shows an enlarged section view of the disphrage in position in pre-actuated and actuated disphragm, such that nowment of the inner sleave will result in an increase in the enclosed volume within the pistom cylinder, bellows or disphragm producing a vacuum or low pressure volume to form the resisting load (force) capable of preventing the actuation of the aerosol valve.

In one embodinent, the sleave for the dispenser will act as a sliding, air tight pistum, except that instead of providing a high pressure volume, downwards notion evay from the main casing creates a low pressure volume.

In a favoured arrangement, the pneumatic resisting means may be formed by the imper sleave and a fixed insert in the outer cheater linked together by flexible bellows or by a sliding air tight seal between the sleave and a cylinder-like extension to the insert.

In a further embodiment, the preload is a spring which operates against the servosol valve. Preferably the preload is applied by a lever, pivoted in a recess bound in the outer chember. The lever may take the form of a restraining lever preventing a loaded spring from acting on the servosol can until operated. After operation the lever is used to reload the spring. Alternatively the lever may be commented via a pluy to a spring which is in contact with the inner elseve such that movement of the lever loads the spring.

It is also preferred that the release device is breath-extuated in order to co-ordinate the release of the sedicasest with the intake of breath. The release devices any comprise a valve port in the cross sember. The valve port say normally be covered by a florible valve flap which on actuation is opened, allowing the prolocal to actuate the serosol valve as pressure in the present thesens returns to the rest state. In the embodisent whereals the resisting force is a positive pressure of air, opening of the valve port releases the built-up pressure, and air escapes from the emclosed volume, allowing the full force of the preload to act against the serosol valve. In the schodinent wherein the renisting force is

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state.

as seen in Figures 1 and 2, an inhalation device consists of a main body 5 which is generally cylindrical in cross section. The main body innludes a solid cross her 10 having a bore 15 across one end of the main body 5. Within the main body 5 a sleave 20 is included having similar cross section to the main body 5. longitudinal axis of both the sleeve 20 and the main body 5 is generally conxist. A known type of serosol dispensing container 25 of generally cylindrical shape is comtained within the sleeve 20. The sleeve 20 includes a circumferential seal 30 arranged in sliding air tight contact with the inner bore 15 of the main body 5. The circumferential seal 30 may be a smal of synthetic rubber or natural rubber. The seal may be an 0-ring extending around the slasve 20. Alternatively the seal 30 could be an integral part of the lip of the slowe 20.

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The aerosol dispensing container 25 has a stem 40 which contains an aerosol dispensing valve (not shown). The hore 15 is such that it forms an air tight seal on the stem 40 of the aerosol dispensing container 25. A shoulder 45 limits and locates the position of the stem 40, which in turn locates the aerosol dispensing container 25 in position in the main body 5. A passage 50 extends from the bore 15, continuing from the shoulder 45 to interconnect with a dispensing couls 55.

As shown in Figure 1, the end of the main body 5, having a pivot 60 has a recess 65 adapted to receive a can lawer 70 operating on the pivot 60. In the rest position, the pivot extends across the recess 65 allowing the can lawer 70 to rotate about the pivot 60. The recess further includes a generally cylindrical passage 75 which receives a spring 80 located between a slidable plog 85 and the

As shown in Figure 2, a can lawer extension 90 when rotated through 90° operates on the plog 85 causing it to

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slide and compress the spring 80.

At the opposite end of the main body 5 is a thpiece 95, separated from the main body by the cross piece 10. The nouthpiece 95 comprises a chamber 100. The dispensing nozzle 55 projects into the chamber 100. The chamber 100 has one or more air inlets 105 such that air may pass from the air inlets 105 to the mouthplace 95. A wane or flep 110 in its rest position divides the Chamber 100 between the air inlets 105 and the nouthpiece 95 [see Figure 1]. The wane 110 is pivoted by means of a pin 115 such that it may move from its rest position towards the nouthpiece by means of pressure drop between the air inlets 105 (see Figure 2) and the nouthpiece 95.

The solid cross number 10 includes a small valve port 120 which is covered by a flexible valve flap 125, biased by its construction to rest in a closed position. The flap 125, pivotally commented to the cross piece 10, acts normally to prevent air flow out of the enclosed space 130 and affectively seal the space 130.

A valve stem 135 extends through the valve port 120 and is nivotally connected to the wans 110. On more of the wans to the actuated position, the stem 135 moves through the valve port 120, causing the flap 125 to be opened. The positioning of the pivoted connection of the valve stem 115 to the vano 110 allows a large movement of the wans to cause a small movement in the valve sten 135, increasing the force applied to the valve flap 125.

In use, the patient loads the agrosol dispensing container into the sleeve 20. The serosol container may be loaded by providing a coarse threaded screw in the main body 5, positioned above the seal 30, for example about the line I-I. When part of the main body 5 has been unsurewed, the inner sleeve 20 can then be slidably removed and the agreeol inserted. The inner sleeve 20 and main body 5 can them be replaced, and the device is ready for use.

Alternatively, the device could be manufactured as a

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95, a small pressure differential is created across the vane 110, which is pivoted at one end. The pressure differential causes the wans 110 to nove from the rest position to the actuated position. The vane 110 and the design of the lower chamber 100 are such that in the actuated position air can flow freely from the air inlets 105 to the patient.

ent of the wans 110 causes the walve stem 135 to move up into contact with and push open the valve flap 125. Opening the valve flap 125 releases the air commressed in the space 130, thus causing an inhalance of forces on the sleeve 20 and container 25. The sleeve 20 and container 25 are forced downwards by the spring 80 resulting in the release of a measured dose of medicament through the dispensing nossle 55 and into the mouthpiece 95 at the some time as the patient breathes in. Thus the Datient inhales air with a petered dose of medicament.

After the inhalation of the dose by the patient, the can lever 70 is returned to the rest position. This releases the load on the spring 80, allowing the sloove 20 and container 25 to nowe back to their original positions under the influence of the internal valve spring. Volume of the enclosed space 130 is increased, and air flows into the space 130 through the flexible valve flap 125 until the pressure in the space 130 returns to atmospheric pressure.

In an alternative errangement as shown in Figure 3, an inhalation device consists of a main body 400 which is merally cylindrical in cross section, with a nouthpiece section 405 at one end and an end cap 407 housing air inlets 420 at the other end. A known type of asrosol dispension container 25 of generally-cylindrical shape is housed within the main body of the device. The serosol dispensing container has a sten 40 which contains an serosol dispensing valve (not shown). The bore 15 is such that it forms an air tight seal on the stem 40 of the serosol dispensing container 15. A shoulder 45 limits and

smaled unit, which is discarded when all the doses in the container have been dispensed.

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The lever 70 is in the rest position [see Figure 1] such that no load is applied via the spring 80 to the sleeve 20. The air space 130 is at atmospheric pressure.

The lever 70 is raised to a loaded position (see Figure 3] and causes the spring \$0 to be compressed by the plus 85, further causing the sleeve 20 and the aerosol container 25 to move downwards. Such povement causes the air in the enclosed space 130 to be compressed. cannot escape through the valve port 120 which is covered by the valve flan 125. The increased air pressure in the space 130 acts to provide a resisting load to prevent the actuation of the aerosol valve. It also increases the effectiveness of the sealing of the valve port 120.

Downward powement of the sleave-20 and container 25 continues until the force being applied by the compressed spring 80 equals the combined force of the internal spring, which actuates the internal valve of the dispensing container, and the force due to the increased sours in the enclosed space 110. The position of the slesve 20 and container 25 when the forces belance is determined by the dimensions of the enclosed space and the spring constant of the spring 80; these are chosen such that the balancing of forces occurs just before the aerosol container 25 has been moved, relative to its stem 40, by a sufficient amount to result in a dose release.

Some standard aerosol containers include a stem hole 135 in the stem 40 of the container. In this case, when the can lover 70 is raised to a loaded position Figure 2, the air trapped in the enclosed space 130 will went wis the stem hole 140, out through pessage 50 and nozzle 55. As the sleeve 20 and container 25 move down further, compressing the internal valve spring, the stem hole 135 is occluded by the valve rubber, and the air in the enclosed space 130 is then compressed.

On inhalation by the patient through the mouthpiece

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locates the position of the stem 40, which in turn locates the acrosol dispensing container 25 in position in the main body 400. A passage 50 extends from the bore 15, continuing from the shoulder 45 to interconnect with a dispensing nozzle 55.

The opposite and of the dispensing contain contained within a sleave 420 of minitar cross section to the main body 400. The longitudinal exis of both the slarve 420 and main body 400 is generally coaxial. The sleave is in loose sliding contact with the inner wall of the main body and may include several rebated grooves 430 in its walls to allow free passage of air in the main body past the sloove. The sleave 420 may be held in place by connection with a disphraga 440 hald in connection with the top of the main body 400, as will now be described. Thus, the sleeve 420 effectively hangs from the top of the main body.

One end of an e.g. moulded flexible dispurage 440 (as shown alone in Figure 4) comprising a rigid disc-like section 441, a flexible generally cylindrical wall section 445 and a stiffer connector section 447, is fitted around a purpose-made groove 450 in the sleeve, e.g. by snapfitting. A further moulded lip 470 on the disphrage provides a song fit for one end of a compression spring 460. The compression spring is thus located and free to ant on the sleeve. The other end of the compression spring is located by an anumlar shoulder 481 in a producinantly cylindrical flanged insert 480 housed in the top section of the main body 400. This insert includes a groove 490 into which the disc-like section 441 of the flexible disphrays 440 is snap-fitted.

The joint between the disphrags connector section 447 and inner sleave groove 450 is arranged to be air tight and the shape of the top surface of the sleave 422 to conform to the internel shape of the disphregs such that in the rest position of the inhalar the two surfaces are in close proxinity, and the enclosed space between them

. very small.

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The cylindrical insert 480 is rotained in place by the end cap 407 fitted into the main body of the device. This forms a chasher 590 between the air inlet slots 420 and the rigid part 441 of the disphraps. The chamber is provided with one or more air patheays 580 such that air say pass from the air inlet slots 420 to the mouthplace 405. The rigid diso-like section 441 of the disphraps also includes a small valve port 495 which is normally covered by a valve seal (flap) 540 housed in a vane 550 pivotally connected to the insert 480.

The vane 550 in its rest position divides the Chamber 590 between the air inlets 420 and the air puthways 580 that link to the mouthplace such that it may move from its rest position by means of a pressure drop between the air inlets and the mouthplace. On movement of the vane to the actuated position the valve seal (flap) 540 is sufficiently moved to open the valve purt 495. (The vane 550 may be biased closed by a light spring flamure, a weight or a magnet not shown.)

As shown in Figure 3, the end of the main body having a pivot 500 has a recess edapted to receive a cms 520 integral with a dust cap 510 operating on the pivot. The recess further includes a passage communicating with a similar passage moulded into the internal wall of the main body 400. A canfollower 530 extending from the lower edge of the inner sleeve 420 ents on the cus such that when the sust cap is in the closed position the inner sleeve is forced by the canfollower to its uppersost position.

When the dust cap is rotated to its open position the cms profile is such that the casfollower is free to move downwards by an assount sufficient to allow actuation of the device.

In its rest position the dust cap 510 is closed, the canfollower 530 restrains the inner slews 420 in its uppermost position such that the enclosed space trupped between the disphraps 440 and the top surface 422 of the

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position to the octuated position. The vane and design of the air passessesy 580 in the chamber 590 are such that in the actuated position air can flow freely from the air inlets 420 to the patient.

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The novement of the vane 550 causes the valve seal (flap) 540 to be noved out of a sealing position with the valve port 4195. Opening the valve port allows air into the gap 660 between the disphraps and inner sleave such that the enclosed space reaches atmospheric pressure. This causes an inhalance of forces exting on the sleave 420 and container 25. The sleave and container are thus forced downwards by the spring 460 resulting in the release of a measured dose of medicament through the dispansing norsis 55 and into the mouthpiece at the same time as the patient breaths in. Thus the patient inhalas air with a setared dose of medicament.

After the imhalation of the does by the patient, the dust cap 510 is returned to its closed position. This rotates the cas 530 and cases the casfollower 530 to be forced upsards. This in turn acts on the inner sleeve 420 soving it upsards to compress the spring 460 and close the gap 600 between the disphrage and inner sleeve top surface 422. This forces air out of the enclosed space 600 which escapes through the valve port 495 lifting the valve seal (flap) 540. Since the valve seal (flap) is only lightly biased to its closed position it presents little resistance to air flow out of the enclosed space. The servosol can is free to return to the rest position under the action of its own aerosol valve spring.

In use the petient loads the aerosol dispensing container into the main body. The aerosol container may be loaded by providing a course threaded screw in the main body 400, for example about the line I-I. When part of the main body 400 has been unscrewed, the aerosol can be inserted. The main body 400 can then be replaced locating the inner sleave over the top end of the can, and the dwice is ready for use. As described previously, the

inner sleeve is at a minimum and the spring 460 is compressed. The valve port 495 is closed by the valve seal (flap) 540 and the sleeve 420 is clear of the top of the acrosol can 25 which is thus unloaded.

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The dust cap is opened rotating the integral can 510 allowing the canfollower 510 to drop by smount AA. The inner sleeve is forced downerds under the action of the oping 460. As the inner sleeve moves downerds the enclosed volume between the dispurege 440 and inner sleeve is increased by a linear equivalent amount A'A', less than or equal to AA. Since the valve port 495 is closed this creates a low pressure volume or near vocum in the space 600 [Figure 5]. The effect of the pressure differential between the enclosed volume 600 and strompheric pressure is such that the inner sleeve tends to resist the action of the spring. As the inner sleeve noves downeards it contacts the servool can 25 and begins compression of the asympto valve (not shown).

Downsard sowment of the immar sleave will continue until there is a balance of forces between the compressive force in the spring 460 and resisting forces created by the pressure differential and compression of the servent valve. The geometry of the device is arranged such that this balance occurs before the servent valve has been sufficiently compressed to actuate it.

A typical excess) requires about 200 force to anomate. The spring 460 should accordingly provide a greater force, praferably 168 to 508 greater.

It may also be possible to arrange for the balance of forces to take place before the inner eleave has contacted the enrosed can, such that the spring force is balanced by the resisting force produced on the inner eleave by virtue of the pressure differential.

On inhalation by the patient through the mouthplecs 405, a small pressure differential is created across the vane 550 which is pivoted towards one end. The pressure differential causes the vane to nove from the rest

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device could be manufactured as a sealed unit.

The device may be provided with means to provide a regulated air flow to the user or inhalar. Thus a sonic davice, e.g. a reed, may be provided which sounds when the inspired air flow is greater than a pre-set level, e.g. above 30 to 50 litres per nimute. The sonic davice may be located in the nouthpiece 95 or below the air inlet 420. The sound produced warms the patient to breathe at a lower

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The device may also be provided with a means such that it will not operate below a certain pre-determined air flow rate, e.g. 10 to 30 litres per minute. In one embodiment the vame 550 or 110 will be biased by a spring such that the predstarmined minimum air flow is mecessary for it to move to its actuated position and enable the valve seal to open.

The main body of a dispensing device, as described in the first or second embodiment of this invention is preferably manufactured from a plastic such as polypropylene, acetal or moulded polystyrene. It may however be manufactured from metal or another suitable material.

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- 1. A dispensing device for use with a drug delivery system comprising a means for releasing a means comprising a means for releasing a means comprising a means for applying a preload capable of actuating the delivery means in the system, a means for applying a resisting pneumatic force capable of preventing actuation of the delivery means, and a release device capable of freeing the resisting pneumatic force to allow the preload to actuate the delivery means and dispense the medicament.
- A device as claimed in Claim 1 wherein the drug delivery system is a pressurised inhalation aerosol having a valve as the delivery means.
- 3. An inhalation actuable dispensing device for use with a pressurised acrossol dispensing contains; comprising a means for applying a preload capable of actuating the internal valve of the acrossol container to release a metered dose of medicasent from the container, a resisting pnemmatic force capable of preventing actuation of the acrossol valve and an inhalation actuated release device capable of countaring the resisting pnemmatic force to allow the medicansent to be dispensed.
  - A dispensing device as claimed in Claim 3 wherein the inhalation actuable means comprises a nowable vane, which on inhalation is capable of moving from a rest position to an actuating position.
  - 5. A dispensing device as claimed in Claim 4 wherein the movemble wane is capable of actuating the release device to allow the prelond to actuate the aerosol valve.
  - a dispensing device as claimed in any one of the preceding claims, further including a receptacle for the

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tight volume selected from a believe, piston, cylinder or disphragm.

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- 14. A dispensing device as claimed in Claim 12 or Claim 13 wherein the prolond comprises a spring acting on the inner elseve enclosing the aerosol, said spring being compressed by a lever acting on the inner elseve.
- 15. A dispensing device as claimed in Claim 14 wherein said lever urges equinst a cas formed upon a rotable cover for said device, such that opening of said cover causes the lever to drop and to release energy stored in the spring to ect upon the inner sleeve which acts upon the serosol container.
- 16. A dispensing device as claimed in any one of the preceding claims wherein the release device comprises a valve port, normally covered by a valve flap, which is capable of being opened on actuation of the device.
- 17. A dispensing device as claimed in any one of Claims 2 to 16 which further comprises a sonic device which will sound a signal when a volume of air passing across the somic devices provides the inhaler with an inspiration rate greater than a pre-set rate.
- 18. A dispensing device as claimed in any one of Claims 4 to 17 therein the wane is bissed such that it will nowe to its actuating position at a predetermined air flow rate, but will not nowe to said actuating position at a rate therebalow.

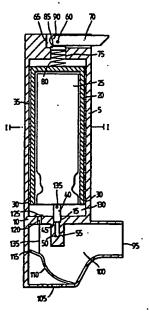
dispensing container comprising an outer chamber having a mouthplece and an inner sleave included within the outer chamber, the inner sleave at least partly enclosing the main body of the serosol container.

- A dispensing device as claimed in Claim 5 wherein the outer chamber includes one or more inlets to allow air to flow to the mouthplets.
- a. A dispensing device as claimed in any one of the preceding claims wherein the preload is applied to the container by use of a spring which operates against the astrosol valve.
- A dispensing device as claimed in any one of Claims 1 to 8 wherein the pnemuntic resisting force comprises a volume of air held at a positive pressure greater than atmospheric.
- 10. A dispensing device as claimed in Claim 9 wherein the positive pressure is created by co-operation of the aerosol container, the inner sleeve and a cross member to form a piston.
- 20 11. A dispensing device as claimed in Claim 9 or Claim 10 wherein the prelocal congrises a lawer pivoted in a recess in the dispensing device, the lawer being connected via a plug to the spring, the spring being capable of acting on the aerosol container.
- 5 12. A dispensing device as claimed in any one of Claims 1 to 8 wherein the premmatic resisting force comprises a volume of air held at a negative pressure below stroogheric.
- A dispensing device as claimed in Claim 12 wherein the negative pressure is created inside an expandable air

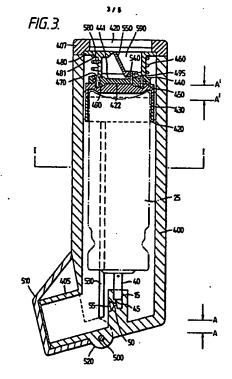
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FIG.1.



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FIG. 4.

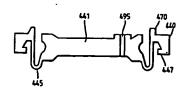
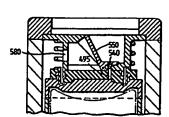
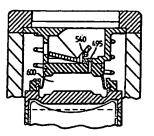


FIG. 5.



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For more details about this manual one Child Journal of the Company Petron Colles, No. 12/02